ORIGINAL CLAIMS

1. (Original) An inclusion complex of aripiprazole in a substituted beta-cyclodextrin.

2. (Original) The inclusion complex as defined in Claim 1 wherein the β-cyclodextrin is sulfobutyl ether β-cyclodextrin (SBECD) or hydroxypropyl β-cyclodextrin (HPBCD).

3. (Original) The inclusion complex as defined in Claim 2 wherein the cyclodextrin is SBECD.

4. (Original) A pharmaceutical formulation comprising aripiprazole and a substituted β-cyclodextrin.

5. (Original) The formulation as defined in Claim 4 in the form of an injectable formulation.

6. (Original) The formulation as defined in Claim 4 wherein the substituted β-cyclodextrin is sulfobutyl ether β-cyclodextrin (SBECD) or hydroxypropyl-β-cyclodextrin (HPBCD).

7. (Original) The formulation is defined in Claim 4 comprising an aqueous injectable formulation having a pH within the range from about 3.5 to about 5.

8. (Original) The formulation as defined in Claim 7 including an acid buffer.

9. (Original) The formulation as defined in Claim 8 wherein the acid buffer is tartaric acid or a salt thereof, citric acid or a salt thereof, hydrochloric acid or a salt thereof, acetic acid or a salt thereof, maleic acid or a salt thereof, malic acid or a salt thereof, sulfuric acid or a salt thereof, toluenesulfonic acid or a salt thereof, benzenesulfonic acid or a salt thereof, naphthalenesulfonic acid or a salt thereof, or ethanesulfonic acid or a salt thereof.

10. (Original) The formulation as defined in Claim 9 further including a base to adjust pH of the aqueous formulation to within the range from about 3.5 to about 5.

11. (Original) The formulation as defined in Claim 8 wherein the substituted β-cyclodextrin is employed in a weight ratio to the aripiprazole within the range from about 10:1 to about 100:1.

12. (Original) The formulation as defined in Claim 8 wherein the acid buffer is employed in a weight ratio to the aripiprazole within the range from about 2:1 to about 10:1.

13. (Original) The formulation as defined in Claim 5 wherein the aripiprazole is present in an amount to provide a dosage from about 1 to 10 mg aripiprazole/mL.

14. (Original) The formulation as defined in Claim 5 wherein the substituted β-cyclodextrin is SBECD and is present in a weight ratio to aripiprazole within the range from about 20:1 to about 40:1.

15. (Original) The formulation as defined in Claim 5 wherein the aripiprazole and the substituted-β-cyclodextrin are in the form of an inclusion complex.

16. (Original) The formulation as defined in Claim 5 wherein the formulation produces minimal irritation at the injection site.

17. (Original) An aqueous injectable formulation comprising aripiprazole, SBECD, tartaric acid, sodium hydroxide and water, said formulation having a pH within the range for about 4 to about 4.6.

18. (Original) The formulation as defined in Claim 17 comprising aripiprazole in an amount to provide from about 1.5 to about 8 mg/mL of formulation, SBECD in an amount with the range from about 100 to about 200 mg/mL; tartaric acid in an amount within the range from about 7 to

about 9 mg/mL sodium hydroxide qs to adjust pH within the range from about 4 to about 4.6; and water qs to 1 mL.

19. (Original) The formulation as defined in Claim 18 wherein the aripiprazole and the SBECD form an inclusion complex.

20. (Original) The formulation as defined in Claim 17 designed for intramuscular administration without causing unacceptable irritation.

21. (Original) The formulation as defined in Claim 15 wherein the inclusion complex provides an amount of aripiprazole of at least 2 mg aripiprazole/mL when the amount of aripiprazole provided by said complex, is measured at a substituted-β-cyclodextrin concentration of 5% w/v in water.

22. (Original) A method for administering injectable aripiprazole to a patient in need of treatment without causing unacceptable irritation at the site of injection, which comprises administering to a patient in need of treatment the formulation as defined in Claim 17.

23. (Original) The method as defined in Claim 22 wherein the formulation is administered intramuscularly.

24. (Original) A method of treating schizophrenia, which comprises administering to a patient in need of treatment the formulation as defined in Claim 5 without causing undue irritation at the site of administration.